K061863 page 1 of 1

510(k) Summary

OCT 19 2006

510(k) Number:

Company:	Arthrex, Inc.
Address:	1370 Creekside Blvd., Naples, FL 34108-1945
Telephone:	(239) 643-5553
Facsimile:	(239) 598-5508
Contact:	Ann Waterhouse, RAC
Device Name:	Arthrex PushLock, Tak, and Corkscrew products
Classification:	Screw, Fixation, Bone, degradable and non-degradable
Product Code:	HWC (21 CFR 888.3040) MBI (21 CFR 888.3040) MAI (21 CFR 888.3030)

Description:

The Arthrex Families which are part of this expanded indications submission are as follows:
Arthrex Bio-Corkscrew and Corkscrew
Arthrex Bio-Corkscrew FT and Corkscrew FT
Arthrex PushLock
Arthrex Tak Family

These implants are comprised of titanium alloy, poly (L-lactide) or PLLA, poly (L-lactide-Co-D, L-lactide) or PLDLA, and Polyaryletherketone or (PEEK). They are offered in several different shapes and sizes. They are offered sterile.

Predicate Devices;

The indication of hip labral repair is substantially equivalent to K053344, Smith & Nephew BioRaptor 2.9 mm and TwinFix Ti 2.8 & 3.5 mm implants.

Indications for Use:

Please see individual indications for use statements, additional indications include Capsular repair and Acetabular labral repair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2006

Arthrex, Inc.
% Ann Waterhouse, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108

Re: K061863
Trade/Device Name: Arthrex Corkscrew, Corkscrew FT, Bio-Corkscrew, and Bio Corkscrew FT Suture Anchor(s)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, JDR, MAI
Dated: September 6, 2006
Received: September 7, 2006

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

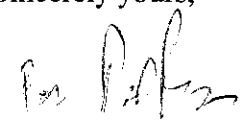
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Arthrex Corkscrew, Corkscrew FT, Bio-Corkscrew, and Bio-Corkscrew FT Suture Anchor(s)

Indications for Use:

The Arthrex Corkscrew Family of Suture Anchors has been previously cleared in 510(k) K003817, K003227, K043337, and K050358. These suture anchors are intended for fixation of suture(soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, elbow, and pelvis in, but not limited to, the following procedures:

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament /Tendon Repair, Bunionectomy .

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Iliotibial Band Tenodesis.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair.

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility of intrinsic sphincter deficiency.

Hip: Capsular repair, acetabular labral repair.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___No___ (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number (if known):

Device Name: Arthrex PushLock™

Indications for Use:

The Arthrex PushLock™, previously cleared under 510(k) K051219, is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, hip, and pelvis in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis repair.

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

Hip: Capsular repair, acetabular labral repair.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___N/A___ (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061463

510(k) Number (if known):

Device Name: Arthrex Tak Family

Indications for Use: The Arthrex Tak™ Family, previously cleared under 510(k)s K971723, K000506, and K050749, is intended to be used for suture or tissue fixation in the foot, ankle, knee, hip, hand, wrist, elbow, shoulder, and in select maxillofacial applications. Specific indications are listed below and are size appropriate per patient needs:

Skull: Stabilization and fixation of oral cranio-maxillofacial skeletal bone, mandible and maxillofacial bones, Lateral Canthoplasty, Repair of Nasal Vestibular Stenosis, Brow Lift, Temporomandibular Joint (TMJ) reconstruction, soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and perioorbital bones of the skull

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

Hip: Capsular repair, acetabular labral repair.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ___X___ AND/OR Over-The-Counter Use ___No___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE) page 3 of 3